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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,709	04/16/2004	Anilkumar Ganapati Gaonkar	77046	1774

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EXAMINER

DONOVAN, MAUREEN C

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,709	Applicant(s) GAONKAR ET AL.	
	Examiner Maureen C Donovan	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 4,5,6,21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "storage temperature" in claims 4,5,6 and 21 is an relative term, which renders the claim indefinite. The term " storage temperature " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The temperature of the food product where the solids fat content is measured is rendered indefinite by the use of the word "storage temperature". Claims 22 is dependent on claim 21 and does not correct the indefinite problem, therefore is also rejected.

Specification

The disclosure is objected to because of the following: On page 5 of the disclosure, lines 12-16, the disclosure states that the Solid Fat Content (SFC) of the lipid layer should change less than 20 weight percent between 20°C and 37°C. This statement contradicts the example given on page15 of the disclosure, wherein the SFC

changes 57% between 20°C and 25°C, which is greater than 20 percent. This statement in the disclosure also contradicts the reasoning given for the less than 20 percent change, which is to "provide a moisture barrier with a rapid and clean melt and a non-waxy mouth feel" (page 5, lines 16-17). One of ordinary skill in the art would not deem a rapid clean melt and non waxy mouth feel to be possible, given a SFC content of 60 to 65 at storage temperature, as also recited in the disclosure (page 5, line 10). One of ordinary skill in the art would expect that with a SFC content of 60-65 at storage temperature, which is a more solid than liquid lipid, and a change of less than 20 percent, that an edible moisture barrier would be consumed that was still substantially solid (therefore not melted) and would yield a considerable waxy mouth-feel. This statement in the specification also contradicts the prior art in the area of edible moisture barriers, which for organoleptic considerations has previously required a change of more than 20 percent in order for the edible moisture barrier to melt rapidly when in contact with mouth temperature. Clarification is required of the statements made in the disclosure with regards to the SFC changing less than 20 weight percent between 20°C and 37°C, and how this does not contradict the example and reasoning also presented in the specification as explained above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,4,5,6,7,11,14,15,16,20,21,22,23,29,32,33,34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cebula, US patent number 5 147 670.

Cebula discloses a multilayer edible moisture barrier comprising at least one lipid layer, wherein the at least one lipid layer comprises an edible low melting triglyceride blend having a melting point of 35°C or lower, and at least one flexible hydrophobic barrier layer, suitable to separate food components having different water activities in a food product (see Column 1, lines 61-64 and Column 4, lines 5-31 and Column 5, lines 4-13), wherein naturally occurring vegetable oils such as hydrogenated soybean oil have melting points below 35°C as evidenced by The Edible Oils Co (see page 1, Hydrogenated Soybean Oil Spec table). Cebula discloses that the edible low melting triglyceride blend is selected from the group consisting of natural, hydrogenated, fractionated and modified vegetable oils such as soybean and sunflower oil (see Column 3, lines 64-68 and Column 4, lines 1-31). Cebula discloses that the lipid layer has a solid fat content of from about 50 to about 100 percent at a storage temperature suitable for the food product onto which the composition is applied (see Column 3, lines 18-32) and wherein the lipid layer has a solid fat content of less than about 3 percent above 37°C (see Column 3, lines 40-45). Cebula discloses that the lipid layer is about 10 microns to about 0.5 mm thick (see Column 4, lines 66-68 and Column 5, lines 1-3), which is within the 50micron to 1mm range of thickness as claimed. Cebula also discloses that the lipid layer comprises a dispersion of solid particles, the solid particles selected from the group consisting of solid particles of chocolate (see Column 4, lines

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50-56) wherein the Office interprets the references teaching of cocoa mass as including solid particles of chocolate. Cebula discloses that the flexible hydrophobic layer is selected from the group consisting of waxes (see Column 5, lines 4-13), wherein a film of paraffin wax is interpreted to be a hydrophobic layer. Cebula also discloses a method for reducing moisture migration between food components having different water activities in a food product, the method comprising applying an edible moisture barrier between the food components, wherein the edible moisture barrier comprises at least 1 lipid layer comprising an edible low melting triglyceride blend having a melting point of 35°C or lower, and at least one flexible hydrophobic barrier layer (see Column 4, lines 57-68 and Column 5, lines 1-25 and Column 5, lines 4-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 8,18,24, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cebula as applied to claims 1,4,5,6,7,11,14,15,16,20,21,22, 23,29,32,33,34 and 36 above, and further in view of Ukai, US patent number 3 997 674.

Cebula discloses all the features of the instantly claimed invention except for the thickness of the hydrophobic layer and that the solid fat content changes less than 20 percent between 20°C and 37°C.

Claims 8 and 24 both claim that the lipid layer has a solid fat content that changes less than about 20 percent between 20°C and 37°C. These claims are in contradiction with teachings of the prior art. Most specifically, Cebula teaches that the solid fat content changes greater than 20 percent over the same temperature range (see Column 4, lines 18-45). One of ordinary skill in the art would expect that a edible moisture barrier would have a solid fat content that changed greater than 20 percent between 20°C and 37°C in order to have a moisture barrier that had a rapid and clean melt. Clarification is required of claims 8 and 24 as to how a lipid layer comparable to the prior art has a property that is in contradiction to what is known in the prior art.

Ukai teaches a flexible hydrophobic layer used as an edible moisture barrier that is about 3 to 100 microns thick (see Column 8, lines 28-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the thickness as taught by Ukai for the hydrophobic barrier as disclosed by Cebula since all are directed to edible moisture barriers and since the thickness as taught by Ukai would provide a low water vapor permeability (see Ukai, Column 8, lines 28-34).

2. Claims 2,3,9,10,12,13,17,19,25,26,27,28,30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cebula as applied to claims 1,4,5,6,7,11, 14,15,16,20,21,22, 23,29,32,33,34 and 36 above, and further in view of Germino, US patent number 4 671 963, Averbach, US patent number 5 130 151 and Sauer, US patent number 5 520 942.

Cebula discloses all the features of the instantly claimed invention except for the lipid layer containing a fat crystal control agent that is less than about 5 microns in size.

Germino teaches an edible moisture barrier composition comprising from 16 to 37 weight percent (see Column 2, Example 1 table) of an edible high melting lipid having a melting point of 100°C or higher (see Column 2, lines 18-22), the edible high melting lipid being calcium stearate (see Column 2, lines 18-22), wherein it is noted that calcium stearate has a melting point of 179-180°C as evidenced by Lange's Handbook of Chemistry (15th Edition, Copyright 1999). The Office interprets the reference to teach the use of a fat crystal control agent as calcium stearate has a high melting point, is lipophilic and is an emulsifier, therefore would inherently be a fat crystal control agent when used in a lipid layer of lower melting triglycerides.

Using calcium stearate as taught by Germino in the invention as disclosed by Cebula would have been obvious to one of ordinary skill in the art at the time of the invention since both are directed to edible moisture barriers and since using calcium stearate will maintain the crunchy and chewy textural characteristics of a food product in the presence of moisture (see Germino, Column 1, lines 41-45).

Sauer teaches an edible moisture barrier composition comprising edible waxes, fats and oils (see Column 8, lines 49-67 and Column 9, lines 1-6) wherein the volume average particle size of the coating is less than 5 microns (see Column 4, lines 57-67 and Column 5, lines 1-9). Note that the office interprets the particle size as taught by Sauer to meet the limitation that the edible high melting lipid is "microparticulated", since if the coating as taught by Sauer is less than 5 microns, and the coating contains high melting lipids, such as waxes, then those high melting lipids are also less than 5 microns.

Incorporating the particle size as taught by Sauer into the invention as disclosed by Cebula in view of Germino would have been obvious to one of ordinary skill in the art at the time of the invention since both are directed to edible moisture barriers and since the particle size as taught by Sauer would increase the surface area available for initial sensory impact, thereby improving the taste of the food product (see Column 5, lines 1-4).

Averbach discloses an edible moisture barrier composition (see Column 2, lines 43-47) comprising: from 1 to 10% weight percent (see Column 8, lines 51-58) of an edible high melting lipid (see Column 6, lines 42-55) having a melting point of 70°C or higher (see Column 6, Table 2) and from 65 to 99 weight percent of an edible low melting triglyceride blend (see Column 4, lines 28-31 and Column 7, lines 39-40).

Using a weight percent of 1-10% of edible high melting lipids in an edible moisture barrier as taught by Averbach in the edible moisture barrier as disclosed by Cebula in view of Germino and Saur would have been obvious to one of ordinary skill in

the art at the time of the invention since all are directed to edible moisture barriers and since the proportion of lipids as taught by Averbach will yield a edible film that will have imperceptible taste, after-taste and mouth feel (see Averbach, Column 4, lines 28-34).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/304446 in view of Fennema and Ukai.

The instant application claims an edible moisture barrier suitable to separate food components having different water activities in a food product, said moisture barrier comprising at least one lipid layer, wherein the at least one lipid layer comprises an edible low melting triglyceride blend having a melting point of 35°C, wherein the at least one lipid layer further comprises an effective amount of a fat crystal control agent (also claimed in Application 10/304446, see claim 1). The instant application claims that the

at least one lipid layer contains about 1 to about 35 percent of the fat crystal control agent and wherein the fat crystal control agent is an edible microparticulated high melting lipid having a melting point of 70°C or higher and a volume average particle size of less than about 10 microns (also claimed in Application 10/304446, see claims 1,7,11,15,16,21). The instant application claims that the lipid layer has a solid fat content of from about 50 to about 70 percent at a storage temperature suitable for the food product onto which the composition is applied (also claimed in Application 10/304446, see claims 2,8,12,22,). The instant application claims that the lipid layer has a solid fat content of less than about 3 percent above 37°C (also claimed in Application 10/304446, see claims 3,23). The instant application claims that the lipid layer has a solid fat content that changes less than about 20 percent between 20°C and 37°C, wherein the edible microparticulated high melting lipid is selected from the group consisting of stearic acid, arachidic acid, behenic acid, lignoceric acid, glyceryl monostearate, glycerol distearate, glycerol tristearate, calcium stearate, magnesium stearate, high melting sucrose polyesters, high melting fatty alcohols, high melting waxes, high melting phospholipids, and mixtures thereof and wherein the edible microparticulated high melting lipid is calcium stearate (also claimed in Application 10/304446, see claims 4,5,9,17,19,24,25,27,31). The instant application claims that the edible low melting triglyceride blend is selected from the group consisting of natural, hydrogenated, fractionated and modified coconut oil, palm kernel oil, rapeseed oil, soybean oil, palm oil, sunflower oil, corn oil, canola oil, cottonseed oil, peanut oil, cocoa butter, anhydrous milkfat, lard, beef fat, acetylated monoglyceride, and mixtures thereof

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(also claimed in Application 10/304446, see claims 6,10,18,26,32). The instant application claims that the at least one lipid layer contains about 6 to about 25 percent of the edible microparticulated high melting lipid and wherein the edible microparticulated high melting lipid has a melting point of 100°C or higher and a volume average particle size of less than about 5 microns, and wherein the lipid layer is about 50 microns to about 1 mm thick (also claimed in Application 10/304446, see claims 7,11,13,,14,20,28,34). The instant application claims a method for reducing moisture migration between food components having different water activities in a food product, said method comprising applying an edible multilayer moisture barrier between the food components, wherein the edible multilayer moisture barrier comprises at least one lipid layer comprising an edible low melting triglyceride blend having a melting point of 35°C or lower (also claimed in Application 10/304446, see claims 29-34).

Copending Application No. 10/304446 does not claim that the edible moisture barrier is multilayered having at least one flexible hydrophobic barrier layer or that the lipid layer further comprises a dispersion of solid particles.

Cebula teaches a moisture barrier comprising at least one lipid layer wherein the lipid layer comprises a dispersion of solid particles, the solid particles selected from the group consisting of solid particles of chocolate (see Column 4, lines 50-56) wherein the Office interprets the references teaching of cocoa mass as including solid particles of chocolate. Incorporating the solid particles as taught by Cebula would have been obvious to one of ordinary skill in the art at the time of the invention since both are directed to edible moisture barriers and since the solid particles of Cebula would provide

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a moisture barrier with flavor that would improve its marketability in the confectionery industry. Cebula also teaches a multilayer edible moisture barrier comprising at least one lipid layer, wherein the at least one lipid layer comprises an edible low melting triglyœride blend having a melting point of 35°C or lower, and at least one flexible hydrophobic barrier layer, suitable to separate food components having different water activities in a food product (see Column 1, lines 61-64 and Column 4, lines 5-31 and Column 5, lines 4-13). Cebula also teaches that the flexible hydrophobic layer is selected from the group consisting of waxes (see Column 5, lines 4-13), wherein a film of paraffin wax is interpreted to be a hydrophobic layer. It would have been obvious to one of ordinary skill in the art to add a hydrophobic layer to the edible moisture barrier as claimed by copending Application No. 10/304446, since both are directed to edible moisture barriers and since an additional moisture barrier layer would provide additional protection to the food product being coated.

Ukai teaches a flexible hydrophobic layer used as an edible moisture barrier that is about 3 to 100 microns thick (see Column 8, lines 28-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the thickness as taught by Ukai for the hydrophobic barrier as claimed by copending Application No. 10/304446 as modified by Cebula since all are directed to edible moisture barriers and since the thickness as taught by Ukai would provide a low water vapor permeability (see Ukai, Column 8, lines 28-34).


This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen C Donovan whose telephone number is (571) 272-2739. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCD


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